Medication Audit Criteria and Guidelines

Mirtazapine (Remeron®)

PEFC Approved: August 2019

Indications

- Akathisia
- Anxiety
- Depressive disorders
- Dysthymia
- Insomnia
- Obsessive-compulsive disorder
- Panic disorder

Black Box Warning

- Increased risk of suicidal thinking and behavior in children, adolescents and young adults (≤ 24 years) taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors.

Contraindications

Absolute

- History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed
- Use of a monoamine oxidase inhibitor within 14 days

Relative

- Pregnancy/nursing mothers

Precautions

- Bipolar disorder in the absence of a mood stabilizer
- Cardiovascular or cerebrovascular disease or conditions that predispose patients to hypotension
- Diagnosis of a seizure disorder or history of seizures
- Discontinuation syndrome
- Hepatic function impairment
- Recovery phase of myocardial infarction
- Renal failure
- Suicidal thoughts and behaviors in children, adolescents, and young adults (≤ 24 years)

Adverse Reactions

Side Effects Which Require Medical Attention

- Agranulocytosis (or signs of infection: sore throat, fever, etc.)
- Dizziness, unsteadiness, lightheadedness or fainting
- Elevated cholesterol
- Elevation in liver enzymes (ALT)
- Increased weight gain/appetite
- Orthostatic hypotension

Pregnancy and Breastfeeding

- See relative contraindications
- Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling

Drug Interactions of Major Significance

- Concomitant monoamine oxidase inhibitors (or within 14 days of an MAOI)

Special Populations

Age-Specific Considerations

- Safety and efficacy have not been established in children younger than 18 years

Patient Monitoring Parameters

- Blood pressure during dosage titration and as clinically indicated (children, adolescents)
- CBC – baseline and as clinically indicated
- Height and weight – baseline, monthly and as clinically indicated (children, adolescents)
- Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – baseline and as clinically indicated. (children, adolescents)

  If no lipid screening has been done within the last year, then a lipid profile should be obtained within 30 days of initiation of the drug
- Monitor for emergence of suicidal ideation or behavior
- Pregnancy test—baseline and as clinically indicated
- Sodium level in high-risk patients (e.g., older than 65 years, previous history of antidepressant-induced hyponatremia, low body weight, concomitant use of thiazides or other hyponatremia-inducing agents, experiencing symptoms of hyponatremia), baseline, 4 weeks and as clinically indicated

Dosing

- See HHSC Psychiatric Drug Formulary for dosage guidelines.
- Exceptions to maximum dosage must be justified as per medication rule.